IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA WESTERN DIVISION No. 5:14-CV-323-D

POLYZEN, INC.,)	
	Plaintiff,)	
v.)	ORDER
RADIADYNE, LLC,)	
	Defendant.	<i>)</i>	

On June 3, 2014, Polyzen, Inc. ("Polyzen" or "plaintiff"), filed suit against RadiaDyne, LLC ("RadiaDyne" or "defendant"), alleging patent infringement [D.E. 1, 2]. On June 25, 2014, RadiaDyne moved to dismiss the suit for lack of subject matter jurisdiction, pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, and to correct ownership of the patent-in-suit, pursuant to 35 U.S.C. § 256 [D.E. 13]. On July 21, 2014, Polyzen responded in opposition [D.E. 16]. As explained below, the court denies RadiaDyne's motion.

I.

The court recites the allegations only briefly because the general background of this case is substantially similar to that in a sister case presently before the court. See Complaint, Polyzen, Inc. v. RadiaDyne LLC, No. 5:11-CV-662-D (E.D.N.C. Nov. 21, 2011), [D.E. 1] ("the 662 case"). Polyzen is the sole assignee of United States Patent No. 8,740,845 ("the '845 patent"). Compl. [D.E. 1] ¶ 10. This patent is entitled "Multi-Layer Film Welded Articulated Balloon." Id. ¶ 9. The patent's first independent claim describes the invention in part as "[a] medical balloon device, comprising a multiplicity of layers of thermoplastic film . . . to enable the device to articulate to a predetermined shape upon inflation of the interior volume with an inflation fluid, to accommodate

a predetermined medical application." <u>Id.</u> ¶ 11; <u>see</u> Patent [D.E. 1-3] 11. Polyzen alleges that RadiaDyne produces medical balloon devices that infringe on multiple independent claims of the '845 patent. Compl. ¶¶ 12–16.

In defending this action, RadiaDyne requests that the court correct the inventorship of the '845 patent and add John Isham, RadiaDyne's CEO, as a co-inventor. See 35 U.S.C. § 256; Def.'s Mem. Supp. Mot. Dismiss [D.E. 14] 6. Section 256 permits a court to "order correction of the patent on notice and hearing of all parties concerned" where a person is, in error, named or omitted as the inventor on an issued patent. 35 U.S.C. § 256(b); Iowa State Univ. Research Found., Inc. v. Sperry Rand Corp., 444 F.2d 406, 408–10 (4th Cir. 1971). Section 256 is a "remedial provision" that allows parties to correct the named inventors on a patent because "a patent issued to but one of joint inventors, upon representation that he is the sol[e] inventor, is void." Iowa State Univ. Research Found., 444 F.2d at 408; see Jamesbury Corp. v. United States, 518 F.2d 1384, 1395 (Ct. Cl. 1975) (per curiam) (adopting opinions of the trial judge). A party challenging inventorship must present clear and convincing evidence to receive relief. Caterpillar Inc. v. Sturman Indus., Inc., 387 F.3d 1358, 1377 (Fed. Cir. 2004); Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1461 (Fed. Cir. 1998). "Clear and convincing evidence is evidence of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established" United States v. Perez, 752 F.3d 398, 407 (4th Cir. 2014) (quotations omitted).

On the current record, RadiaDyne has not presented clear and convincing evidence that Isham was a co-inventor of the '845 patent. Joint inventorship requires that a co-inventor:

(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of

the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.

Israel Bio-Eng'g Project v. Amgen, Inc., 475 F.3d 1256, 1263–64 (Fed. Cir. 2007) (quotation omitted). An alleged co-inventor cannot rely on his or her testimony alone. Ethicon, 135 F.3d at 1461. Rather, the court must examine other evidence, such as contemporaneous documents prepared by the purported co-inventor, to corroborate the co-inventor's testimony. Id.

RadiaDyne cites the following evidence: a patent for a "minimally invasive rectal balloon apparatus" issued to Isham, an email Isham sent to Polyzen, and the transcript of a hearing before this court in the 662 case. See [D.E. 14-5–14-7]. The court already considered most of this evidence in the 662 case and denied RadiaDyne's motion for summary judgment to correct ownership of a related patent. See Order at 1, Polyzen, Inc. v. RadiaDyne LLC, No. 5:11-cv-662-D (E.D.N.C. Oct. 31, 2013), [D.E. 88]. Here, RadiaDyne has not provided clear and convincing evidence that Isham meets the three Israel Bio-Engineering Project factors. For example, the testimony that RadiaDyne cites concerning the instructions Isham gave to Polyzen about creating a balloon with a distal bulge does not sufficiently prove that Isham did anything more than suggest to Polyzen the desired result and offer limited feedback on the acceptability of the balloon prototypes, which is insufficient to constitute inventorship. See, e.g., Def.'s Mem. Supp. Mot. Dismiss 8–10; Nartron Corp. v. Schukra U.S.A. Inc., 558 F.3d 1352, 1359 (Fed. Cir. 2009); Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1359 (Fed. Cir. 2004). Thus, this motion fails.

RadiaDyne also contends that the court lacks subject matter jurisdiction to hear Polyzen's case because Polyzen has failed to include as plaintiffs all co-owners of the '845 patent—specifically RadiaDyne, the assignee of Isham, a purported co-inventor of the '845 patent. Mot. Dismiss [D.E. 13] 1–2; see Fed. R. Civ. P. 12(b)(1); Israel Bio-Eng'g Project, 475 F.3d at 1264–65 ("Absent the

voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing."); Ethicon, 135 F.3d at 1468. RadiaDyne impermissibly, albeit creatively, attempts to flip the burden of proving inventorship to Polyzen by arguing that the burden for establishing standing "lies squarely on the party claiming subject matter jurisdiction." Def.'s Mem. Supp. Mot. Dismiss [D.E. 14] 13 (quoting Mirant Potomac River, LLC v. U.S. EPA, 577 F.3d 223, 226 (4th Cir. 2009)). Here, Polyzen has established standing by virtue of its status as sole assignee of the '845 patent. See Patent 2. "Patent issuance creates a presumption that the named inventors are the true and only inventors." Caterpillar, 387 F.3d at 1377; see Israel Bio-Eng'g Project, 475 F.3d at 1263; Ethicon, 135 F.3d at 1460. A person challenging inventorship may rebut this issuance presumption by clear and convincing evidence. Caterpillar, 387 F.3d at 1377.

Were RadiaDyne to produce clear and convincing evidence that Isham was a co-inventor of the '845 patent and evidence that RadiaDyne is a co-owner, RadiaDyne's arguments about a lack of subject matter jurisdiction would have force. Cf. Miller v. Brown, 462 F.3d 312, 316 (4th Cir. 2006). RadiaDyne, however, has not produced such evidence. Thus, the court may rely on the presumption that applies concerning named inventors upon patent issuance. See, e.g., Caterpillar, 387 F.3d at 1377. Accordingly, RadiaDyne's motion to dismiss for lack of subject matter jurisdiction fails.

II.

In sum, the court DENIES RadiaDyne's combined motion to dismiss for lack of subject matter jurisdiction and to correct ownership of the '845 patent [D.E. 13].

SO ORDERED. This 18 day of December 2014.

AMES C. DEVER III

Chief United States District Judge